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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,515	07/08/2003	Alex Gutteridge	674575-2004	9209

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EXAMINER	
KOSSON, ROSANNE	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/615,515	GUTTERIDGE ET AL.	
	Examiner	Art Unit	
	Rosanne Kosson	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-63* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicants' response to the restriction requirement Office action of March 3, 2005, received on September 1, 2005, is acknowledged. Applicants have pointed out that their application was filed under 35 USC §111 and not 35 USC §371. Accordingly, the previous restriction requirement is withdrawn and is replaced with the following.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I, claim(s) 1-4, 11-23, 37 and 50-52, drawn to a polypeptide comprising SEQ ID NO: 2, classified in class 530, subclass 350.

Group II, claim(s) 1, 2, 5-7, 11-23, 37 and 50-52, drawn to a polypeptide comprising SEQ ID NO: 4, classified in class 530, subclass 350.

Group III, claim(s) 1, 3, 8-10, 11-23, 37 and 50-52, drawn to a polypeptide comprising SEQ ID NO: 6, classified in class 530, subclass 350.

Group IV, claim(s) 24-26, 29-31, 37, 48, 50-52 and 60, drawn to a purified nucleic acid molecule encoding SEQ ID NO: 2, classified in class 536, subclass 23.5.

Group V, claim(s) 24, 25, 27, 29-31, 37, 48, 50-52 and 60, drawn to a purified nucleic acid molecule encoding SEQ ID NO: 4, classified in class 536, subclass 23.5.

Group VI, claim(s) 24, 25, 28, 29-31, 37, 48, 50-52 and 60, drawn to a purified nucleic acid molecule encoding SEQ ID NO: 6, classified in class 536, subclass 23.5.

Group VII, claim(s) 32-33, 37, 50, 52 and 61, drawn to a ligand that specifically binds to SEQ ID NO: 2, classified in class 530, subclass 387.1.

Group VIII, claim(s) 32-33, 37, 50, 52 and 61, drawn to a ligand that specifically binds to SEQ ID NO: 4, classified in class 530, subclass 387.1.

Group IX, claim(s) 32-33, 37, 50, 52 and 61, drawn to a ligand that specifically binds to SEQ ID NO: 6, classified in class 530, subclass 387.1.

Group X, claim(s) 34-36, 37, 50 and 52, drawn to a compound that either increases or decreases the level of expression or the activity of SEQ ID NO: 2, classified in class 536, subclass 24.5.

Group XI, claim(s) 34-36, 37, 50 and 52, drawn to a compound that either increases or decreases the level of expression or the activity of SEQ ID NO: 4, classified in class 536, subclass 24.5.

Group XII, claim(s) 34-36, 37, 50 and 52, drawn to a compound that either increases or decreases the level of expression or the activity of SEQ ID NO: 6, classified in class 536, subclass 24.5.

Group XIII, claim(s) 38-40, 46 and 56, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 2, or assessing the activity of a polypeptide comprising SEQ ID NO: 2, relative to a control, the method comprising binding a ligand to the polypeptide, classified in class 435, subclass 7.1.

Group XIV, claim(s) 38-40, 46 and 56, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 4, or assessing the activity of a polypeptide comprising SEQ ID NO: 4, relative to a control, the method comprising binding a ligand to the polypeptide, classified in class 435, subclass 7.1.

Group XV, claim(s) 38-40, 46 and 56, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 6, or assessing the activity of a polypeptide comprising SEQ ID NO: 6, relative to a control, the method comprising binding a ligand to the polypeptide, classified in class 435, subclass 7.1.

Group XVI, claim(s) 41-42, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 2, or assessing the activity of a polypeptide comprising SEQ ID NO: 2, relative to a control, the method comprising binding a nucleic acid probe or primer to the gene encoding SEQ ID NO: 2, classified in class 435, subclass 6.

Group XVII, claim(s) 41-42, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 4, or assessing the activity of a polypeptide comprising SEQ ID NO: 4, relative to a control, the method comprising binding a nucleic acid probe or primer to the gene encoding SEQ ID NO: 4, classified in class 435, subclass 6.

Group XVIII, claim(s) 41-42, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 6, or assessing the

activity of a polypeptide comprising SEQ ID NO: 6, relative to a control, the method comprising binding a nucleic acid probe or primer to the gene encoding SEQ ID NO: 6, classified in class 435, subclass 6.

Group XIX, claim(s) 43-45, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 2, or assessing the activity of a polypeptide comprising SEQ ID NO: 2, relative to a control, the method comprising detecting the presence of a mutation in the gene encoding SEQ ID NO: 2, classified in class 435, subclass 6.

Group XX, claim(s) 43-45, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 2, or assessing the activity of a polypeptide comprising SEQ ID NO: 2, relative to a control, the method comprising detecting the presence of a mutation in the gene encoding SEQ ID NO: 2, classified in class 435, subclass 6.

Group XXI, claim(s) 43-45, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 2, or assessing the activity of a polypeptide comprising SEQ ID NO: 2, relative to a control, the method comprising detecting the presence of a mutation in the gene encoding SEQ ID NO: 2, classified in class 435, subclass 6.

Group XXII, claim(s) 47 and 49, drawn to a method of using SEQ ID NO: 2 as an adhesion molecule, classified in class 514, subclass 2.

Group XXIII, claim(s) 47 and 49, drawn to a method of using SEQ ID NO: 4 as an adhesion molecule, classified in class 514, subclass 2.

Group XXIV, claim(s) 47 and 49, drawn to a method of using SEQ ID NO: 6 as an adhesion molecule, classified in class 514, subclass 2.

Group XXV, claim(s) 53-55, drawn to a method of treating disease, comprising administering a polypeptide comprising SEQ ID NO: 2, or a pharmaceutical composition thereof, classified in class 514, subclass 2.

Group XXVI, claim(s) 53-55, drawn to a method of treating disease, comprising administering a polypeptide comprising SEQ ID NO: 4, or a pharmaceutical composition thereof, classified in class 514, subclass 2.

Group XXVII, claim(s) 53-55, drawn to a method of treating disease, comprising administering a polypeptide comprising SEQ ID NO: 6, or a pharmaceutical composition thereof, classified in class 514, subclass 2.

Group XXVIII, claim(s) 53-55, drawn to a method of treating a disease, comprising administering a nucleic acid molecule that encodes SEQ ID NO: 2, or a pharmaceutical composition thereof, classified in class 514, subclass 44.

Group XXIX, claim(s) 53-55, drawn to a method of treating a disease, comprising administering a nucleic acid molecule that encodes SEQ ID NO: 4, or a pharmaceutical composition thereof, classified in class 514, subclass 44.

Group XXX, claim(s) 53-55, drawn to a method of treating a disease, comprising administering a nucleic acid molecule that encodes SEQ ID NO: 6, or a pharmaceutical composition thereof, classified in class 514, subclass 44.

Group XXXI, claim(s) 53-55, drawn to a method of treating a disease, comprising administering a ligand that specifically binds to SEQ ID NO: 2, or a pharmaceutical composition thereof, classified in class 424, subclass 9.34.

Group XXXII, claim(s) 53-55, drawn to a method of treating a disease, comprising administering a ligand that specifically binds to SEQ ID NO: 4, or a pharmaceutical composition thereof, classified in class 424, subclass 9.34.

Group XXXIII, claim(s) 53-55, drawn to a method of treating a disease, comprising administering a ligand that specifically binds to SEQ ID NO: 6, or a pharmaceutical composition thereof, classified in class 424, subclass 9.34.

Group XXXIV, claim(s) 57, drawn to a method of identifying a compound that is effective in treating or diagnosing disease, comprising selecting a compound that specifically binds to SEQ ID NO: 2, classified in class 435, subclass 7.1.

Group XXXV, claim(s) 57, drawn to a method of identifying a compound that is effective in treating or diagnosing disease, comprising selecting a compound that specifically binds to SEQ ID NO: 4, classified in class 435, subclass 7.1.

Group XXXVI, claim(s) 57, drawn to a method of identifying a compound that is effective in treating or diagnosing disease, comprising selecting a compound that specifically binds to SEQ ID NO: 6, classified in class 435, subclass 7.1.

Group XXXVII, claim(s) 57, drawn to a method of identifying a compound that is effective in treating or diagnosing disease, comprising selecting a compound that specifically binds to a nucleic acid molecule encoding SEQ ID NO: 2, classified in class 514, subclass 44.

Group XXXVIII, claim(s) 57, drawn to a method of identifying a compound that is effective in treating or diagnosing disease, comprising selecting a compound that

specifically binds to a nucleic acid molecule encoding SEQ ID NO: 4, classified in class 514, subclass 44.

Group XXXIX, claim(s) 57, drawn to a method of identifying a compound that is effective in treating or diagnosing disease, comprising selecting a compound that specifically binds to a nucleic acid molecule encoding SEQ ID NO: 6, classified in class 514, subclass 44.

Group XL, claim(s) 58-59, drawn to a kit comprising a first container comprising a nucleic acid probe that hybridizes to a gene encoding SEQ ID NO: 2 and a second container comprising a primer for amplifying a gene that encodes SEQ ID NO: 2, classified in class 536, subclass 23.1.

Group XLI, claim(s) 58-59, drawn to a kit comprising a first container comprising a nucleic acid probe that hybridizes to a gene encoding SEQ ID NO: 4 and a second container comprising a primer for amplifying a gene that encodes SEQ ID NO: 4, classified in class 536, subclass 23.1.

Group XLII, claim(s) 58-59, drawn to a kit comprising a first container comprising a nucleic acid probe that hybridizes to a gene encoding SEQ ID NO: 6 and a second container comprising a primer for amplifying a gene that encodes SEQ ID NO: 6, classified in class 536, subclass 23.1.

Group XLIII, claim(s) 62, drawn to a transgenic or knock-out animal that expresses a higher, a lower or no level of SEQ ID NO: 2, classified in class 800, subclass 9.

Group XLIV, claim(s) 62, drawn to a transgenic or knock-out animal that expresses a higher, a lower or no level of SEQ ID NO: 4, classified in class 800, subclass 9.

Group XLV, claim(s) 62, drawn to a transgenic or knock-out animal that expresses a higher, a lower or no level of SEQ ID NO: 6, classified in class 800, subclass 9.

Group XLVI, claim(s) 63, drawn to a method of screening for a compound to treat disease, comprising contacting a transgenic animal that expresses a higher, a lower or no level of SEQ ID NO: 2 with a candidate compound, classified in class 800, subclass 3.

Group XLVII, claim(s) 63, drawn to a method of screening for a compound to treat disease, comprising contacting a transgenic animal that expresses a higher, a lower or no level of SEQ ID NO: 4 with a candidate compound, classified in class 800, subclass 3.

Group XLVIII, claim(s) 63, drawn to a method of screening for a compound to treat disease, comprising contacting a transgenic animal that expresses a higher, a lower or

no level of SEQ ID NO: 6 with a candidate compound, classified in class 800, subclass 3.

The inventions are distinct, each from the other because of the following reasons.

In their election of a group, Applicants should note that they must choose **ONE** protein SEQ ID NO. from among SEQ ID NOS. 2, 4 and 6 or ONE DNA sequence that encodes one of SEQ ID NOS. 2, 4 or 6. Each sequence is a distinct invention requiring separate searches. These are NOT species. The proteins of SEQ ID NOS. 2, 4 and 6 are structurally distinct molecules that function to produce distinct antibodies and that bind different ligands and interact with different enhancers, inhibitors and co-factors. As a result, these proteins are patentably distinct.

Applicants should also note that searching each polypeptide or polynucleotide sequence imposes a serious search burden. Currently, there are approximately eight different databases that accompany the results of a search for one discrete amino acid sequence or nucleotide sequence, and each result set from a particular database must be carefully and separately considered with respect to the prior art. Hence, the search for even two different polypeptides or polynucleotides, or two different polypeptide or polynucleotide segments in the databases, in addition to searching the organic molecule and text databases, would require extensive searching and review.

Therefore, any group drawn to product related to SEQ ID NO: 2 is a distinct and separate invention from any group drawn to a product related to SEQ ID NO: 4 or 6.

Each of Groups I – XII and XL – XLV is drawn to a different product. Groups I, IV, VII, X, XL and XLIII are related to SEQ ID NO: 2. But, the protein of SEQ ID NO: 2 and the DNA encoding the protein of SEQ ID NO: 2 (Groups I and IV) are distinct inventions because the protein can be made by other and materially distinct processes, such as by protein synthesis or by purification from the natural source. The DNA molecule has utility for the recombinant production of the protein in a host cell, but can

be used for other processes, such as nucleic acid hybridization assays. Further, these two molecules are structurally, chemically and functionally different. This protein molecule and this DNA molecule are different from a ligand that binds to the protein of SEQ ID NO: 2 (Group VII), because Group VII is drawn to a molecule that may have any structure and whose chemical, physical and biological properties are different than those of the molecules of Groups I and IV. Therefore, these inventions are patentably distinct. The protein, the DNA and the ligand are different from a compound that increases or decreases the activity or expression of the protein of SEQ ID NO: 2 (Group X), because Group X is drawn to a molecule that may have any structure and whose chemical, physical and biological properties are different than those of the molecules of Groups I, IV and VII. Therefore, these inventions are patentably distinct. The protein, the DNA, the ligand and the enhancer/inhibitor are different from a kit comprising a probe and a primer that hybridize to a gene that encodes SEQ ID NO: 2 (Group XL), because Group XL is drawn to a composition comprising two oligonucleotides of unspecified length. This composition is a combination of two molecules whose function and whose chemical, physical and biological properties are different than those of the molecules of Groups I, IV, VII and X. Therefore, these inventions are patentably distinct. The protein, the DNA, the ligand, the enhancer/inhibitor and the kit are different from the transgenic or knock-out animal of Group XLIII, because Group XLIII is drawn to an animal. The ligand, enhancer/inhibitor and kit are not required for producing this animal and may be used for purposes other than in connection with this animal, such as various protein and DNA assays. The protein is not required for producing the animal,

and the DNA is not used for producing the animal if it is a knock-out. The DNA also has other uses, such as in detection assays or in recombinant fermentations. Therefore, these six inventions are patentably distinct.

Analogously to the foregoing, the inventions of Groups II, V, VIII, XI, XLI and XLIV are related to SEQ ID NO: 4, but are patentably distinct (protein, DNA, ligand, enhancer/inhibitor, kit and transgenic/knock-out animal). Analogously to the foregoing, the inventions of Groups III, VI, IX, XII, XLII and XLV are related to SEQ ID NO: 6, but are patentably distinct (protein, DNA, ligand, enhancer/inhibitor, kit and transgenic/knock-out animal).

Each of Groups XIII, XVI, XIX, XXII, XXV, XXVIII, XXXI, XXXIV, XXXVII and XLVI is drawn to a different method. Each of these groups is related to SEQ ID NO: 2. But, each of these groups is a distinct invention because each of these methods has different functions, different modes of operation and/or different effects. These ten methods are as follows: a method of binding a ligand to a polypeptide to diagnose disease (XIII); a method of binding a probe or primer to a gene to diagnose disease (XVI); a method of detecting a mutation in a gene to diagnose disease (XIX); a method of using a protein as an adhesion molecule (XXII); a pharmaceutical method of treating disease comprising administering a protein (XXV); a gene therapy method of treating disease comprising administering a DNA molecule (XXVIII); a pharmaceutical method of treating disease comprising administering a ligand (XXXI); a method of identifying a compound that treats or diagnoses disease comprising selecting a compound that specifically binds to a protein (XXXIV); a method of identifying a compound that treats or

diagnoses disease comprising selecting a compound that specifically binds to a DNA molecule (XXXVII); and a method of identifying a compound that treats disease comprising contacting a transgenic animal that expresses a higher, a lower or no level of a particular protein with the compound. Additionally, each diagnostic method is based on a different set of molecules, each treatment method is based on a different set of molecules, and each drug screening method is based on a different set of molecules. Unrelated to disease is a method of using a protein molecule as an adhesion molecule, which recites no steps. Therefore, each of these methods is patentably distinct.

Analogously to the foregoing, the inventions of Groups XIV, XVII, XX, XXIII, XXVI, XXIX, XXXII, XXXV and XXXVIII, respectively, are related to SEQ ID NO: 4, but are patentably distinct (three diagnostic methods, one use method, three treatment methods and two screening methods). Analogously to the foregoing, the inventions of Groups XV, XVIII, XXI, XXIV, XXVII, XXX, XXXIII, XXXVI and XXXIX, respectively, are related to SEQ ID NO: 6, but are patentably distinct (three diagnostic methods, one use method, three treatment methods and two screening methods).

As noted above, because any one protein sequence or any one polynucleotide sequence is a separate invention, an invention related to SEQ ID NO: 2 is patentably distinct from an invention related to SEQ ID NO: 4 or 6, or visa versa.

Regarding a combination of a group drawn to a product and a group drawn to a method in which the claims in each group are drawn to the same SEQ ID NO., for example, Group I and Group XIII, XVI, XIX, XXII, XXV, XXVIII, XXXI, XXXIV, XXXVII, or

XLVI, the protein of Group I is not required for practicing the methods of Groups XVI, XIX, XXVIII, XXXVII or XLVI. The protein of Group I may used other than in the diagnostic method of Group XIII, because it may be used as an adhesion molecule (i.e., to bind to a receptor to maintain homeostasis in a normal subject). The protein of Group I may used other than in the treatment method of Group XXV, because it may be used as an adhesion molecule (i.e., to bind to a receptor to maintain homeostasis in a normal subject). Because the protein of Group I may be used in a treatment method or in a diagnostic method, it may be used other than in the method of Group XXII to maintain homeostasis. Because the protein of Group I may be used in a diagnostic method, or as an adhesion molecule to maintain homeostasis, or in a treatment method by being administered, it may be used other than in the treatment method of Group XXXI in which a ligand of the protein is administered. Because the protein of Group I may be used as an adhesion molecule to maintain homeostasis, or in a treatment or diagnostic method, it may be used other than in the drug screening method of Group XXXIV.

The nucleic acid molecule of Group IV is not required for practicing the methods of Groups XIII, XXII, XXV, XXXI, XXXIV or XLVI. The nucleic acid molecule of Group IV is also not required for practicing the method of Group XVI, as a small fragment of a DNA molecule, such as a small fragment of SEQ ID NO: 1, a fragment which does not encode the protein of SEQ ID NO: 2, could and normally would be used. The nucleic acid molecule of Group IV may be used in a method other than the diagnostic method of Group XIX, as it may be used to produce protein in a recombinant culture or

fermentation. The nucleic acid molecule of Group IV may be used in a method other than the treatment method of Group XXXVII, as it may be used to produce protein in a recombinant culture or fermentation.

The ligand of Group VII is not required for practicing the methods of Groups XVI, XIX, XXII, XXV, XXVIII, XXXIV, XXXVII or XLVI. The ligand of Group VII may be used other than in the diagnostic method of Group XIII, because it may be used to detect the presence of the protein to which it binds in any in vitro sample, such as in a method to purify the recombinant protein. The ligand of Group VII may be used other than in the treatment method of Group XXXI, because it may be used to detect the presence of the protein to which it binds in any in vitro sample, such as in a method to purify the recombinant protein.

The enhancer/inhibitor molecule of Group X is not required for practicing the methods of Groups XIII, XVI, XIX, XXII, XXV, XXVIII, XXXI, XXXIV, XXXVII or XLVI.

The kit of Group XL is not required for practicing the methods of Groups XIII, XXII, XXV, XXVIII, XXXI, XXXIV, XXXVII or XLVI. The kit of Group XL may be used other than in the method of Group XVI to measure a gene expression level, because it may be used to amplify the polynucleotide encoding SEQ ID NO: 2 for cloning. The kit of Group XL may be used other than in the mutation detection method of Group XIX, because it may be used to amplify the polynucleotide encoding SEQ ID NO: 2 for cloning.

The transgenic/knock-out animal of Group XLIII is not required for practicing the methods of Groups XIII, XVI, XIX, XXII, XXV, XXVIII, XXXI, XXXIV or XXXVII. This

animal may be used other than in the drug screening method of claim XLVI, such as in methods of studying the effect of an abnormal level of a specific gene, such as SEQ ID NO: 1, on the animal as a whole, or the effect on metabolic pathways.

Therefore, any of Groups I, IV, VII, X, XL or XLIII is a patentably distinct invention from any of Groups XIII, XVI, XIX, XXII, XXV, XXVIII, XXXI, XXXIV, XXXVII or XLVI.

Analogously to the foregoing, with respect to SEQ ID NO: 4, none of Groups II, V, VIII, XI, XLI or XLIV is required exclusively for practicing any of the methods of Groups XIV, XVII, XX, XXIII, XXVI, XXIX, XXXII, XXXV or XXXVIII. As a result, any of these combinations recites patentably distinct inventions.

Analogously to the foregoing, with respect to SEQ ID NO: 6, none of Groups III, VI, IX, XII, XLII or XLV is required exclusively for practicing any of the methods of Groups XV, XVIII, XXI, XXIV, XXVII, XXX, XXXIII, XXXVI or XXXIX. As a result, any of these combinations recites patentably distinct inventions.

As noted above, because any one protein sequence or any one polynucleotide sequence is a separate invention, an invention related to SEQ ID NO: 2 is patentably distinct from an invention related to SEQ ID NO: 4 or 6, or visa versa.

Additionally, the search for any one group differs from the search for any other group, thereby creating an undue burden of search and examination. Burden lies not only in the search of U.S. patents, but in the search for literature and foreign patents and examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness and scope of enablement. Further, the

different groups have each acquired a separate status in the art, as shown in part by their different classifications. Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is clearly proper.

Further, this application contains claims directed to the following patentably distinct species of the claimed invention. The species are as follows:

a) each of the compounds listed in claim 36;

b) each of the diseases listed in claim 46;

c) each of the diseases listed in claim 52;

d) each of the abnormal expression levels listed in claim 62- higher or lower or absent;

e) each of the abnormal expression levels listed in claim 63- higher or lower or absent.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species in each of a) - e) above for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. The following claim(s) are generic: 36, 38, 52, 62 and 63.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product

claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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